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EXAMINER

LUM, LEON YUN BON

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,988

Applicant(s)

NADAOKA ET AL.

Examiner

Leon Y. Lum

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-14,16-23,25-33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-14,16-23,25-33 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/6/02; 5/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 29 June 2005 is acknowledged and has been entered.
2. In regards to claim 16, the previous Office Action mistakenly failed to indicate that the claim was rejected in the main body of the action. The instant claim should have been rejected with claims 9, 28, and 35 over Burd et al in view of Allen et al. The Examiner apologizes for the omission and submits that Burd et al and Allen et al references necessarily read on claim 16, which claims a cavity part of less than 100 μ l, since the rejection of claims 9, 28, and 35 is over a cavity part of less than 20 μ l, which would necessarily include any volume above 20 μ l. Since an additional reference is not needed to cover claim 16 and since Applicants have not objected to the omission in the previous Office Action, the mistake is corrected in the instant Office Action and clarified for the record. Once again, the Examiner apologizes for the inadvertent omission in the previous Office Action.

Information Disclosure Statement

3. The information disclosure statement filed 02 May 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A copy has not been

provided for foreign patent documents EP 0 447 154 and EP 0 903 584. They have been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 10-13, 17-18, 20-23, 29-32, 36-37, and 39-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burd et al (US 5,939,331).

In the instant claims, Burd et al reference teaches a device (i.e. biosensor) with a test strip 13 (i.e. development layer) that contains a label zone 26 (i.e. marker reagent holding part) and a capture zone 29 (i.e. reagent immobilization part), wherein the capture zone 29 contains at least one capture reagent capable of interaction with the label after sample fluid moves from sample zone 23 through label zone 26 to capture zone 29 (i.e. marker reagent can be eluted by the development of the inspection target solution). See column 8, line 2 to column 10, line 14; and Figures 1-2. In addition, Burd et al reference teaches a top cover 17 with sample introduction aperture 35 (i.e. space forming part located on said development layer that forms a cavity part) that allows for

the introduction of the sample into the sample zone 23 (i.e. into which the inspection target solution flows by a capillary phenomenon), wherein the label zone 26 is above and slightly overlapping the sample zone 23 (i.e. marker reagent holding part in the cavity part). See column 9, lines 33-43 and column 10, lines 4-7; and Figures 1-2.

With respect to claim 2, since the sample introduction aperture 35 is placed directly over the sample zone 23, and the label zone 26 overlaps the sample zone 23, as stated above, the label zone 26 is also therefore under the introduction aperture 35, and reads on the limitation of “marker reagent holding part in said cavity part” (lines 10-12).

With regards to claims 3-4, 10, 22-23, and 29, Burd et al reference teaches that the sample introduction aperture 35 allows for the introduction of the sample into the sample zone 23, wherein the sample then flows through label zone 26 and into capture zone 29 (i.e. volume of said cavity part controls an amount of the inspection target solution flowing inwards). See column 9, lines 33-43 and column 10, lines 4-7; and Figures 1-2. Since the fluid does not stay in the introduction aperture 35, the aperture does not permanently contain the fluid (i.e. the cavity part temporarily holds the inspection target solution; means for externally checking on whether the inspection target solution flowed inwards or not).

With regards to claims 11 and 30, Burd et al reference teaches that the top cover 17 (i.e. space forming part) includes an indicator aperture 37 that is on top of window 15 wherein the binding of label can be observed through a thin, clear or translucent material (i.e. partially light permeable). See column 9, lines 33-36 and Figure 1.

With regards to claims 12 and 31, Burd et al reference teaches that the sample zone 23 contains reagent capable of binding and retaining red blood cells while allowing RBC-free fluid to flow into the remainder of the device (i.e. a separation part). See column 9, lines 57-62.

With regards to claims 13 and 32, Burd et al reference teaches sample zone 23 (i.e. a specimen holding part) below introduction aperture 35 (i.e. cavity part), as stated above. See column 9, lines 57-58 and Figure 1.

With regards to claims 17 and 36, Burd et al reference teaches a series of slits 39 in the top cover 17 for the evaporation of fluid from the absorbent zone (i.e. an air vent). See column 9, lines 46-47 and Figure 1. With regards to the phrase "for assisting the \ inspection target solution in flowing into the cavity part" in the instant claims, the phrase is an intended use of the limitation "air vent" and is therefore not given patentable weight.

With regards to claims 18 and 37, Burd et al reference teaches that the membranes employed may allow for either bibulous or non-bibulous flow, wherein non-bibulous membranes will have a pore size of about 1-00 μm (i.e. a porous material which can be permeated by permeation of the inspection target solution in the cavity part). See column 2, line 67 to column 3, line 48.

With regards to claims 20-21 and 39-40, Burd et al reference teaches the flow of sample fluid through label and capture zones on nitrocellulose with reagent antibodies and label that bind and indicate the presence of analyte (i.e. employed for a one-step immuno-chromatography). See column 9, line 33 to column 10, line 14.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Bernstein et al (US 5,824,268).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a cell component destruction reagent.

Bernstein et al reference teaches a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. See column 10, lines 49-54.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. The membrane of Bernstein et al has the advantage of purifying a test sample for use in the device of Burd et al, thereby providing motivation for including the membrane in the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a membrane containing ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in the device of Burd et al, since Burd et al teach the prevention of red blood cells from flowing past the sample zone 23 (i.e. part in

the cavity), and a membrane that lyses red blood cells is one type of device to prevent passage of red blood cells.

10. Claims 7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Killeen et al (US 5,166,051).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a cell component shrinkage reagent.

Killeen et al reference teaches a crenating agent in a membrane that functions to shrink RBC, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. See column 5, lines 36-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with a crenating agent in a membrane that functions to shrink RBC, as taught by Killeen et al, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. The crenating agent of Bernstein et al has the advantage of purifying a test sample for use in the device of Burd et al, thereby providing motivation for including the agent in the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had

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reasonable expectation of success in including a membrane containing a crenating agent to shrink cells, as taught by Killeen et al, in the device of Burd et al, since Burd et al teach the prevention of red blood cells from flowing past the sample zone 23 (i.e. part in the cavity), and a membrane that crenates cells is one type of device to prevent passage of cells.

11. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Barr (US 4,252,538).

Burd et al reference has been disclosed above, and teaches that sample zone 23 contains reagents that retain red blood cells (i.e. part in the cavity), as stated above, but fails to teach that sample zone 23 contains a bleaching reagent.

Barr reference teaches distilled water that bleaches red blood cells, in order to cause rupture of the membrane and produce transparent red blood cells. See column 10, lines 14-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with distilled water that bleaches red blood cells, as taught by Barr, in order to cause rupture of the membrane and produce transparent red blood cells. The distilled water of Burd et al has the advantage of supplying clear red blood cells without optical contaminants in the device of Burd et al, thereby providing motivation of including distilled water in the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including in the device of Burd et al, since Burd et al teach an

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immunochromatographic assay with the prevention of whole red blood cells from flowing past the sample zone 23 (i.e. part in the cavity), and the distilled water of Barr causes the lysis of red blood cells, and is one means of preventing whole red blood cells from flowing past the sample zone 23 such that the transparent red blood cells would not affect detection of coloration in the immunochromatographic assay.

12. Claims 9, 16, 28, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Allen et al (US 5,416,000).

Burd et al reference has been disclosed above, but fails to teach that the cavity part has a volume of 20 μ l or less.

Allen et al reference teaches a sample receiving element that receives about 10 μ l volume of blood, in order to receive one or a series of small drops of blood. See column 5, lines 19-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with a sample receiving element that receives about 10 μ l volume of blood, as taught by Allen et al, in order to receive one or a series of small drops of blood. The cavity volume taught by Allen et al has the advantage of requiring just one or two drops of blood in the device of Burd et al, thereby providing motivation for combining the cavity volume with the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a sample receiving element that receives about 10 μ l volume of blood, as taught by Allen et al, in the device of Burd et al, since both Burd

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et al and Allen et al disclose blood as sample fluid, and the sample receiving element of Allen et al is in an immunochromatographic test strip. See column 7, line 41.

13. Claims 14 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Woudenberg et al (US 6,124,138).

Burd et al reference has been disclosed above, but fails to teach that the specimen holding part holds a larger amount of inspection target solution than the volume of the cavity part.

Woudenberg et al reference teaches a dead-end fluid connection 86 (i.e. cavity part) dimensioned to define a volume that is substantially less than the volume of the associated detection chamber 84 (i.e. specimen holding part), in order to ensure that the detection chamber is sufficiently filled with sample. See column 9, lines 3-14 and Figure 5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Burd et al with a dead-end fluid connection 86 (i.e. cavity part) dimensioned to define a volume that is substantially less than the volume of the associated detection chamber 84 (i.e. specimen holding part), as taught by Woudenberg et al, in order to ensure that the detection chamber is sufficiently filled with sample. The volume difference as taught by Woudenberg et al has the advantage of ensuring that the detection chamber has enough sample to perform a test, thereby providing motivation for combining the volume difference in the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had reasonable

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expectation of success in including a fluid connection with less volume than a detection chamber, as taught by Woudenberg et al, in the method of Burd et al, since Burd et al teach the transfer of fluid from the introduction aperture (i.e. cavity part) to the sample zone (i.e. specimen holding part) is from an opening to an interior chamber, and the fluid connection and detection chamber of Woudenberg are, respectively, an opening and interior chamber.

14. Claims 19 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al (US 5,939,331) in view of Kloefer (US 4,883,764).

Burd et al reference has been disclosed above, but fails to teach that whole reagents including the reagent in the reagent immobilization part and the marker reagent are in a dry state and they are entirely in a dry state.

Kloefer reference teaches reagents in dry form on the test strip, in order to improve the chemical stability of the reagents. See column 6, lines 26-32.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Burd et al with reagents in dry form on the test strip, as taught by Kloefer, in order to improve the chemical stability of the reagents. The dry reagents of Kloefer have the advantage of being chemically stable and not volatile, thereby providing motivation for including the dry form of reagents in the device of Burd et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including dry reagents, as taught by Kloefer, in the apparatus of Burd et al, since both Burd et al and Kloefer teach test strips.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/069,845 in view of Burd et al (US 5,939,331).

Claims 1-40 of the instant application recite a biosensor comprising a development layer for developing an inspection target solution as a specimen by making the inspection target solution permeate inwards, wherein said development layer includes a reagent immobilization part immobilized therein and a marker reagent holding part where a marker reagent which can be eluted by the development of the inspection target solution is held, wherein said biosensor measures a bonding amount of the marker reagent in said reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution,

and wherein said biosensor further comprises a space forming part which forms, by being located on said development layer, a cavity part, wherein said cavity part is a space into which the inspection target solution flows by a capillary phenomenon, and a marker reagent holding part for holding a marker reagent which can be eluted by flowing-in of the inspection target solution, in said cavity part.

Claims 1-25 of the copending application discloses a biosensor comprising a development layer wherein an inspection target solution is developed, and further comprising at least a marker reagent part where a marker reagent is held so as to be dissolved by the development of the inspection target solution in a part of the development layer, as well as a reagent immobilization part where a reagent which specifically reacts to an analysis target in the inspection target solution is immobilized in a part of the development layer. Claims 1-25 of the copending application also disclose directional permeation of the inspection target solution. With regards to the limitation "measures a bonding amount of the marker reagent in said reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution" in the instant application, since the copending application is a biosensor that develops an inspection target solution and also comprises a marker reagent part and reagent immobilization part, the device of the copending application would necessarily have the capability of measuring "a bonding amount" between the marker reagent and the reagent immobilization part, which would inherently include either "qualitatively or quantitatively" measuring components in the inspection target solution.

However, claims 1-25 of the copending application fails to teach a space forming part, by being location on said development layer, a cavity part that, wherein said cavity part is a space into which the inspection target solution flows by a capillary phenomenon, and also fails to teach that the marker reagent is held in the cavity part.

Burd et al reference teaches a top cover 17 (i.e. space forming part) with sample introduction aperture 35 (i.e. cavity part) to allow for the introduction of the sample into a sample zone 23 (i.e. between the development layer and the space forming part), in order for sample to interact with the sample zone prior to a label zone and other parts of the biosensor. In addition, Burd et al reference teaches that the label zone 26 is above and slightly overlapping the sample zone 23 (i.e. marker reagent holding part in the cavity part). See column 9, lines 33-43 and column 9, line 57 to column 10, line 14; and Figures 1-2. Since the introduction aperture 35 (i.e. cavity part) is placed directly over the sample zone 23, and the label zone 26 (i.e. marker reagent holding part) overlaps the sample zone 23, as stated above, the label zone 26 is also therefore under the introduction aperture 35, and reads on the limitation of "marker reagent holding part in the cavity part".

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus in claims 1-25 of the copending application with a top cover 17 (i.e. space forming part) with sample introduction aperture 35 (i.e. cavity part) to allow for the introduction of the sample into a sample zone 23 (i.e. between the development layer and the space forming part), as taught by Burd et al, in order for sample to interact with the sample zone prior to a label zone and other parts of the

biosensor. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a top cover with sample introduction aperture over a sample zone, as taught by Burd et al, with claims 1-25 of the copending application since claims 1-25 of the copending application teach a biosensor with parts that interact with an inspection target solution in series, and the introduction of sample through a sample introduction aperture in a top cover, as taught by Burd et al, is one type of method to introduce a target solution into a biosensor at one location for interaction with different biosensor parts in series.

This is a provisional obviousness-type double patenting rejection.

17. The above provisional obviousness-type double patenting rejection is representative of double patenting rejections that are necessary between the instant application and a number of copending applications. The following list discloses the serial numbers of the other copending applications which would require similar provisional obviousness-type double patenting rejections as applied supra: 10,133,698 (claims 1 and 3-17); 10,398,711 (claims 1-19); 10,048,727 (claims 1-11); 10,116,407 (claims 1-5); 10,242,672 (claims 14-17).

Response to Arguments

18. Applicant's arguments, see pages 11-12 of the Remarks, filed 29 June 2005, with respect to the foreign priority and information disclosure statement objections made in

the previous Office Action have been fully considered and are persuasive. The said objections of have been withdrawn.

19. Due to Applicant's claim amendments, as described on pages 13-14 of the Remarks, the rejections of claims 1-40, based on 35 U.S.C. 112, 2nd paragraph, have been overcome.

20. On pages 14-16 of the Remarks, Applicants argue that Burd et al reference fails to teach the limitation of a space forming part that forms a cavity part in claim 1. Specifically, Applicants contend that the sample introduction part 35 in Burd et al is not formed by the placement of the top cover 17 since the sample introduction part is always present regardless of the location of top cover 17, and that the instant claim requires that the cavity part is formed through placement of the space forming part on the development layer. See page 16.

Applicant's arguments have been fully considered, but are not found convincing. Burd et al teach that the sample introduction aperture 35 may be in any shape or size. See column 9, lines 38-42. In addition, Burd et al teach that the label zone 26 overlaps the sample zone 23. See column 10, lines 4-7; and Figure 1. Since the top cover 17 is placed over the test strip 13 such that the sample introduction aperture is aligned on top of the sample zone, and the label zone 26 overlaps the sample zone, the device requires an empty space directly above the sample zone and under the aperture in order to accommodate label zone. In addition, since the sample introduction aperture

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can be of any size or shape, the device allows for an aperture that is smaller than the surface area of the sample zone. The combination of an aperture smaller than the surface of the sample zone, and an empty space in between the sample zone and top cover, necessarily produces a cavity that is enclosed on the top by the top cover, except at the aperture, and on the bottom by the sample zone. Since the cavity is not formed until the top cover is placed on top of the test strip, Burd et al anticipate the instant limitation.

Applicant's arguments are therefore not found to be convincing and the rejection set forth in the previous Office Action is maintained.

Conclusion

21. No claims are allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

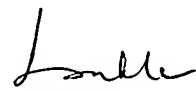
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641



LYL



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/14/05